



GIMA

PROFESSIONAL MEDICAL PRODUCTS

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TERMOMETRO AURICOLARE A RAGGI INFRAROSSI PROFESSIONALE

PROFESSIONAL INFRA-RED EAR THERMOMETER

THERMOMÈTRE AURICULAIRE À RAYONS INFRAROUGES PROFESSIONNEL

TERMÓMETRO INFRARROJO DE OÍDO PROFESIONAL

Manuale d'uso - User manual
Manuel de l'utilisateur - Guía de Uso



ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

REF 25575 / THP59J



Radiant Innovation Inc.
1F, No.3, Industrial East 9th Road,
Science-Based Industrial Park, HsinChu, Taiwan 300

EC REP

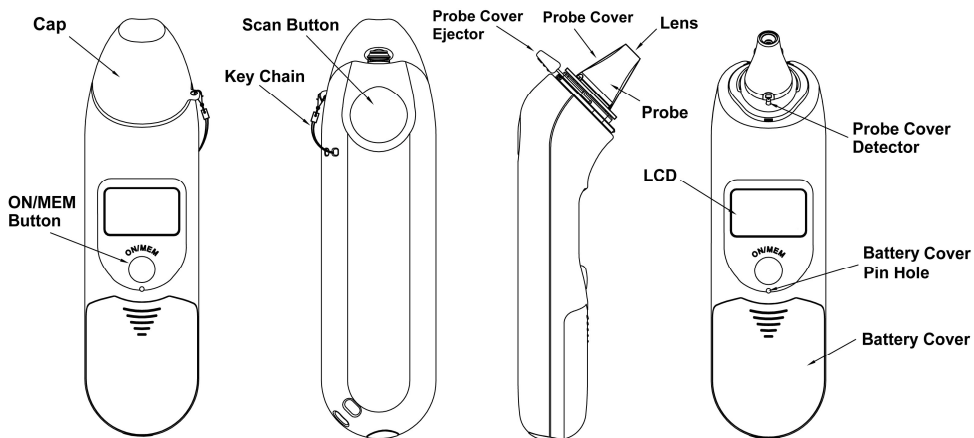
Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80, D-66386 St. Ingbert, Germany

IP22



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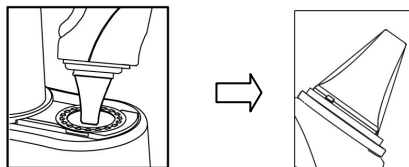


Intended use: The infrared ear thermometer measures the infrared heat generated by the eardrum and surrounding tissue to reflect patient's body temperature.

Operating Instructions
Temperature taking

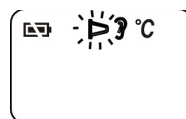
Place the Probe Cover

1. Align the the probe with the center of the probe cover.
 Make sure to place the **"Adhesive Side"** of probe cover **"Upward."**
2. Insert the probe into the probe cover on the probe cover loader until you feel a "click".
 That means the probe cover has been connected firmly.



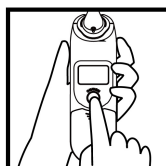
- ⚠️ *1. Proper installation of the probe cover and using the specific probe cover ensure accurate measurements.*
- 2. Warning: Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.*

If the probe cover did not install well, ▷ will flash on the LCD screen and can't take the ear temperature (will hear 4 beep sounds without reading shown on the LCD when measuring). Please check the setting of the probe cover again.

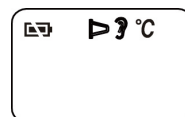


Power ON

1. Press "ON/MEM" button
2. See the icon ? on the LCD and hear two beep sounds



1

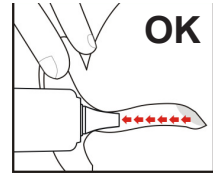
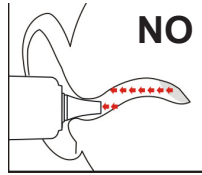


2

Taking Ear temperature

Gently pull the ear back to straighten the ear canal and snugly position the probe into the ear canal, aiming towards the membrane of the eardrum to obtain an accurate reading.

- For children under 2 years old
Pull the ear straight back.
- For children over 2 years old and adults
Pull the ear straight up and back.




0-2 years



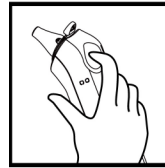
> 2 years

Measuring

Press the “Scan” button for 1 second until you hear a long beep sound. The measurement is completed. You can read the result from LCD. After two short beeps are heard, the  icon stops flashing to be ready for next measurement.

Fever Indication:

If the thermometer detects a body temperature $\geq 37.5^{\circ}\text{C}$ (99.5°F), three short beep sound will follow one long beep sound to warn the user for potential fever.



Press “Scan” button

Power Off

Automatically shut down after 1 minute pending to extend battery life.


Attentions



- The device must stay in stable ambient (room) temperature for 15 minutes before operating.*
- Before the measurement, please stay in a stable environment for 5mins and avoid the exercise, bath for 30mins.*
- It is recommended that you measure the same ear for 3 times. If the 3 measurements are different, select the highest temperature.*
- The thermometer has been designed for practical use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. Please consult with doctor if you have health concerns.*

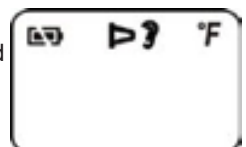
Other Functions

Memory Locations (25 sets)

When power on, press the “ON/MEM” button to see the temperature records with  icon.

To change the LCD from $^{\circ}\text{C}$ to $^{\circ}\text{F}$:

In “Power Off” mode, press and hold the “SCAN” button, then press the “ON/MEM” button for 3 seconds, icon “ $^{\circ}\text{C}$ ” will be switched to icon “ $^{\circ}\text{F}$ ”. You can also use the same process to change the LCD display from $^{\circ}\text{F}$ to $^{\circ}\text{C}$.





Specifications

- Temperature measurement range: 34~42.2°C (93.2~108°F)
- Operating temperature range: 10~40°C (50~104°F), 15%~85% RH
- Storage temperature range: It should be stored at room temperature between -20~+50°C, RH ≤85%
- Transportation temperature shall be less than 70°C, RH ≤95%
- Atmospheric pressure: 800~1013 hPa
- Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993, RoHS.
- Accuracy: ±0.2°C (0.4°F) within 35~42°C (95~107.6°F)(Ambient Temp.:15~35°C), ±0.3°C (0.5°F) for other range.
- Fever indication & Memory, °C / °F Switch function
- Battery: one lithium cell battery (CR2032 x 1pcs).
- Battery life: around 3,000 continuous readings.
- Expected Service Life: 4 years
- This thermometer converts the ear temperature to display its “oral equivalent.” (according to the result of the clinical evaluation to get the offset value)
- Enclosure Rating: IP22
- Dimensions: 144.8 x 48.5 x 39.8 mm
- Weight: 68.8 grams including battery

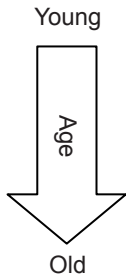


The device should not submerge into any liquids and expose it to direct moisture. There is no gender and age limitation for using infrared thermometer. This is not an AP or APG product

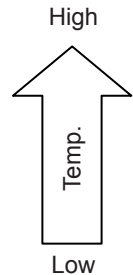
Normal body temperature

Normal body temperature is a range that will fluctuate throughout the day. The normal range for adult body temperature is typically considered to be 36.1 to 37.8°C (97 to 100°F). The body temperature varies by age, person, gender, time of day, position of body, and is usually highest in the evening. It can be affected by activity, emotion, clothing, medications, ambient conditions, hormones and other factors. Normal temperature will also be different depending on the place on the body at which the temperature is taken, with rectal or ear temperature readings generally being higher than oral temperature readings, and armpit temperature readings generally lower than oral readings.

Temperature variations affected by age:



0~2 years:	36.4°C (97.5°F) ~ 38.0°C (100.4°F)
3~10 years:	36.1°C (97.0°F) ~ 37.8°C (100.0°F)
11~65 years:	35.9°C (96.6°F) ~ 37.6°C (99.7°F)
>65 years:	35.8°C (96.4°F) ~ 37.5°C (99.5°F)



The “Clinical Bias” is -0.2 ~ -0.4°C.
The “Limits of Agreement” is 0.49.
The “Repeatability” is 0.14°C.

Important Notes

Cleaning and storage

The probe is the most delicate part of the thermometer. Use with care when cleaning the lens to avoid damage.



**** Replace the probe cover after each use to ensure an accurate reading and avoid cross contamination.**

- Storage temperature range: It should be stored at room temperature between $-20\sim+50^{\circ}\text{C}$, RH $\leq 85\%$
- Transportation temperature shall be less than 70°C , RH $\leq 95\%$
- Keep the unit dry and away from any liquids and direct sunlight.
- The Probe should not be submerge into liquids

**** If device is accidentally used without probe cover, clean the probe as follows:**

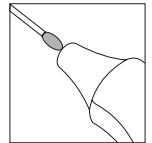
- After the measurement, please use the cotton swab with the Alcohol (70% concentration) to clean the lens(on the inside of the probe).
- Allow the probe to fully dry for at least 1 minute.



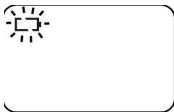
Note: Please check if the device is damaged once it drops.

If you can't make sure of it, please send the complete device to your local dealer for recalibration.

Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.



Battery replacement



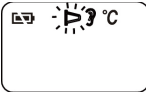

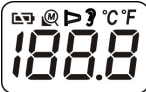
This device is supplied with one lithium cell CR2032 x 1.

- Open the battery cover: Insert a pointed object into battery cover pick hole. At the same time, use thumb to push battery cover out.
- Hold the device and flip the battery out with a small screwdriver.
- Insert the new battery under the metal hook on the left side (1) and press the right side (2) of the battery down until you hear a "Click".
- Replace the battery cover



The positive (+) side up and the negative (-) side pointed down.

Trouble shooting

Error Message	Problem	Solution
	The probe cover has not been installed well.  will flash on the LCD screen and can't take the ear temperature	Please check the setting of the probe cover again. (Refer to the section of "Place the Probe Cover")
Er	Error 5~9, the system is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.
Er 1	Measurement before device stabilization.	Wait until all the icons stops flashing.
Er 3	The ambient temperature is not within the range between 10°C and 40°C (50°F ~104°F).	Allow the thermometer to rest in a room for at least 15 minutes at room temperature: 10°C and 40°C (50°F ~104°F).
H₁	Temperature taken is higher than +42.2°C (108°F)	Check the integrity of the probe cover and take a new temperature measurement.
Lo	Temperature taken is lower than +34°C (93.2°F)	Make sure the probe cover is clean and take a new temperature measurement.
	Device cannot be powered on to the ready stage.	Change with a new battery.



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.

This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA.

During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included.

All components subject to wear are not included in the warranty.













The repair or replacement performed during the warranty period shall not extend the warranty.

The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use.


GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.

The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.

The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

Symbols				
	Medical Device complies with Directive 93/42/EEC		Product code	 WEEE disposal
	Caution: read instructions (warnings) carefully		Type BF applied part	 Covering Protection rate
	Follow instructions for use		Manufacturer	 Authorized representative in the European community
	Keep away from sunlight		Keep in a cool, dry place	 Lot number

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1KHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1KHz	<p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following </p>

NOTA 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTA 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	contact ± 8 Kv air $\pm 2, \pm 4, \pm 8,$ ± 15 kv	contact ± 8 Kv air $\pm 2, \pm 4, \pm 8,$ ± 15 Kv	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60Hz	30 A/m 50 Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150KHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.7GHz $d = 2.3 \sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The device is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the device should assure that it is used in such an environment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) $\square \pm 5$ kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.